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ASSESSMENT OF POST-OPERATIVE PAIN AFTER USING TWO FORMULATIONS OF CALCIUM HYDROXIDE INTRACANAL MEDICATION: A RANDOMIZED CLINICAL TRIAL.

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KEYWORDS

Calcium hydroxide, intracanal medication, iodoform, symptomatic apical periodontitis, post-endodontic pain

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ABSTRACT

Introduction: Application of intracanal medicament in infected root canals in-between endodontic visits is targeted for additive disinfection as well as post-operative pain prevention. **Aim:** to elucidate the palliative effect of calcium hydroxide through comparative study of the post-endodontic pain in patients with necrotic pulp associated with symptomatic apical periodontitis using a modified visual analogue scale (MVAS). **Materials and methods:** Sixty patients with single-rooted lower premolars diagnosed with pulp necrosis with symptomatic apical periodontitis were included in the study. The participants were divided into three groups; Two experimental and one control (n=20 per group): G I (control group) root canals did not receive any intra canal medication, GII: root canals received calcium hydroxide intracanal medication without iodoform, and root canals in G III received calcium hydroxide intracanal medication with iodoform. All three groups received glass ionomer coronal temporization by glass ionomer. The patients recorded their pain scores in (MVAS) pre-operatively ,4, 6, 12, 24, 48, 72 hrs and after one week. **Results:** At all-time intervals, no significant change was detected in the pain scores in-between the experimental and control groups ($P<0.05$). **Conclusion:** Calcium hydroxide with /without iodoform has neutral effect on post-operative pain.

INTRODUCTION

Post-endodontic pain is a multifactorial complicated condition. The following categories could be used to group the contributing factors: factors related to the host which include demographic data, immune response of the patient, psychological status, factors that could be linked to the operator such as poor disinfection, over-instrumentation and extrusion of chemical or obturating material and others related to the tooth including tooth location in the arch, macro and micro anatomy`[(1)].

Intracanal medication is recommended between visits for added disinfection of the root canal dentin within the intricate internal anatomy, which could play an indirect pathway for reducing post-operative pain [(2)]. The gold standard intracanal medication is calcium hydroxide ($Ca(OH)_2$)[(3)].

The antibacterial efficacy of calcium hydroxide paste could be augmented by biological active vehicles for instance camphorated paramonochlorophenol, chlorhexidine, and iodine based materials[(4)].

The bacteriostatic property of iodoform occurs by releasing free iodine. Iodine precipitates proteins and oxidizes essential enzymes, thus eliminating the root canal and periapical tissue infection [5].

The proposed null hypothesis is no significant difference is expected between the control group, calcium hydroxide with/without iodoform as intracanal medicament in cases diagnosed by necrosis with symptomatic apical periodontitis.

Therefore, this study aimed to elucidate the palliative effect of calcium hydroxide through comparative study of the post-endodontic pain in patients diagnosed with necrotic pulp associated with symptomatic apical periodontitis after been medicated by calcium hydroxide intracanal medication with /without iodoform using a modified visual analogue scale (MVAS).

MATERIALS AND METHODS

The study was a randomized clinical trial with parallel arm design with 1:1 allocation ratio. The Preferred Reporting Items for Randomized Trials in Endodontics (PRIRATE) 2020 were used as a guide for the layout of the current study methodology [6]. Complying with the World Medical Association Declaration of Helsinki (version 2008). The current proposal was recorded at www.ClinicalTrials.gov ((26/08/2021), study identifier: (NCT05021809) (Figure 1). The Research Ethical Committee of faculty of Dentistry, Suez Canal University accepted the study proposal (360/2021). All methods were according to the relevant guidelines and regulations. A consent was acquired from all participants explaining the study procedures and the related possible complications.

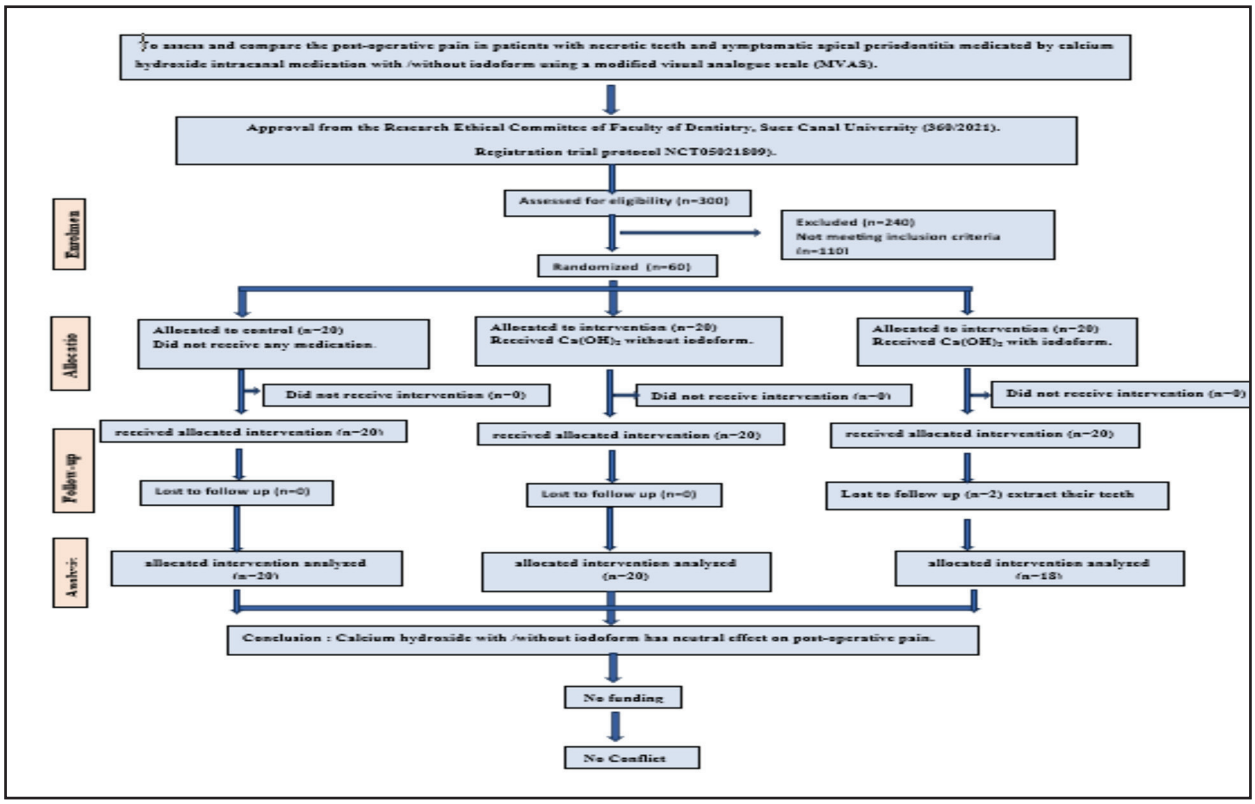

Fig. (1) The PRIRATE flowchart Nagendrababu et al. [6]

I. Patients and clinical data:

Sample size calculation:

Sample size calculation was carried out to compare between different treatments using G*power version 3.1.9.5[7]. Participants were divided into three groups; 54 patients were sufficient to perceive an effect of 0.3 at a significant level of (α) level of 0.05, with a power (1-β) of 80%. Consequently, a total sample size of 60 patients were recruited for this study to account for any loss within 10% during the follow-up periods.

Study population:

Sixty patients indicated for root canal treatment were chosen from the Endodontic department's outpatient clinic at the faculty of Dentistry, Suez Canal University with the following criteria:

Patients ages between 18 and 50 years old, with mature single-rooted lower premolars with root canal type I Vertucci's classification with pulpal necrosis and obvious pain under percussion, periapical index score PAI 3[8]. Exclusion criteria: Open apex, swelling, non-restorable, root caries, vital pulp, periodontal pocket with probing depth >4mm or previous root canal treatment. Patients who had received pre-operative analgesics and patients who had antibiotics prescription in the past three months. Patients with uncontrolled systemic diseases, pregnant or lactating females as well.

Randomization, concealment, and blindness

Cases were divided in random fashion using a computer-generated random number into three groups, the coded papers were kept in an opaque envelope till the patient chose his/her own paper. Blind allocations were followed in the study by the patient and the statistician. However, it was impossible to the operator to be blind due to the difference in colour between the two medications.

Sample Grouping:

The selected cases were divided as follow; two experimental and one control (n=20 per group): GI (control group) root canals did not receive any intra canal medication, G II: root canals received calcium hydroxide intracanal medication without iodoform (Metapaste (Meta Biomed, Chungcheong, Korea), and root canals in G III received calcium hydroxide intracanal medication with iodoform (Metapex (Meta Biomed, Chungcheong, Korea)).

Root canal preparation and medication:

Root canal treatment was performed in two appointments, patients were instructed to fill the MVAS at the beginning of the first visit to act as the baseline. Under proper isolation, an access cavity was prepared. Electronic apex locator was used to determine the working length (Root ZX II, J Morita, Tokyo, Japan) followed by periapical x-ray for confirmation (Dentsply Sirona, New York, U.S.A.). Bio-mechanical preparation of the root canals was performed using a new set of ProTaper Next rotary files (Dentsply-Maillefer, Ballaigues, Switzerland) till X4, irrigation protocol was performed using 5ml of 2.5% sodium hypochlorite (NaOCl (Wilson, Sao Paulo, Brazil) between each file using side vented needle (Ultradent, Utah, U.S.A). Afterwards, the root canals were irrigated using 1 ml of 17% Ethylene Diamine Tetra acetic Acid (EDTA (Prevest Denpro, Jammu, India)) for 1 min, then 5ml NaOCl followed by 5ml saline and dried by absorbent paper point (Meta Biomed, Chungcheong, Korea). In the control group, teflon was placed in the pulp chamber then temporization using glass ionomer (Prevest Denpro, Jammu, India). In the other two groups the intracanal medication was injected according to the

manufacturer instructions, complete filling of the root canal was confirmed by periapical x-ray.

One week later, at the beginning of the second appointment , the patient was instructed to fill MVAS. The medicament was then removed, and the root canals were filled using cold lateral compaction technique. After that, the access cavity was sealed using glass ionomer and composite restoration (3M, New York, U.S.A). Unfortunately, two cases in GIII were absent in the second appointment.

Evaluating measures:

Patients filled the MVAS in order to measure post-endodontic pain intensity in the three groups. According to ***Emad et al.*** [9], the following criteria were: 0 represented no pain, mild pain (1-3), moderate pain (4-6), severe tolerable pain was 7-9 and severe intolerable pain was represented by 10. The pain score was recorded pre-operatively, 4, 6, 12, 24, 48, 72 hrs. and one week later after the application of the intracanal medication for follow-up.

Statistical Analysis

Data were presented as median, range, mean values in addition to standard deviation (SD) values. One-way ANOVA test compared the parametric data between mean age values among the three groups. The Kruskal-Wallis test compared the non-parametric data among all groups. Friedman's test was to study the changes within each group. When Friedman's test is significant, pair-wise comparisons were performed using Dunn's test. The significance was established at $P \leq 0.05$.

RESULTS

All cases were analyzed in each group after intervention (n=20) except two lost cases in G III (n=18) during follow-up.

Demographic data of the patients

Table 1 showed that no significant difference was detected between the mean age values neither between gender values in the two experimental groups in addition to the control group.

Table (1) *Mean, standard deviation (SD), frequencies (n), percentages as well as results of ANOVA and Chi-square tests.*

	G I No medication (n = 20)	G II Metapaste (n = 20)	G III Metapex (n = 18)	*P*-value
Age (Years)				
Mean (SD)	31.5 (4.7)	34.4 (6.7)	34.9(8.9)	0.255
Gender [n (%)]				0.926
Male	7 (35)	6 (30)	6 (30)	
Female	13 (65)	14 (70)	14 (70)	

**: Significant at $P \leq 0.05$.*

Pain (MVAS) scores

Quantitative data experienced in pain ratings.

I. Intragroup analysis:

G I (control group), G II (Metapaste group)as well as G III (Metapex group) revealed that there was a significant change by time in median pain scores (P-value <0.05, Effect size = 0.281, Effect size = 0.455, Effect size = 0.627 respectively). In G I, comparing pairs of data from different time periods showed that the median pain scores declined significantly four hrs following the treatment moreover, between 24 and 48 hrs. A significant increase in pain scores was found only between 4 to 6 hrs. From six to 12,12 to 24, 48 to 72 hrs as well as from 72 hrs. to one week; no significant change in pain ratings was detected. On other hand, pair comparisons between time periods in G II

(Metapaste group) revealed a significant decrease in median pain scores after 4 hrs, from 12 to 24 hrs and from 72 hrs to one week. A significant rise in pain scores from four to six hrs. was detected. From six to 12 hrs, from 24 to 48 in addition to the period from 48 to 72 hrs; there was no significant change in pain ratings. The pairs comparison between time intervals in G III (Metapex group) showed no significant change in median pain scores between time periods except significant decline in pain scores occurred from 24 to 48 hrs and from 72 hrs to one week. (**Table 2**)

II. Intergroup analysis:

There was no significant change between the pain scores among all groups; Pre-operatively, after four, six, twelve, twenty-four , forty-eight, seventy-two hrs. as well as after one week (*P*-value = 0.306, Effect size = 0.028), (*P*-value = 0.357, Effect size = 0.042), (*P*-value = 0.616, Effect size = 0.019), (*P*-value = 0.628, Effect size = 0.02), (*P*-value = 0.327, Effect size = 0.043), (*P*-value = 0.796, Effect size = 0.011), (*P*-value = 0.949, Effect size = 0.005) and (*P*-value = 0.064, Effect size = 0.066), respectively. (**Table 2**)

Table (2) *Descriptive statistics and results for pain (MVAS) scores of Friedman's test within each group and Kruskal-Wallis test between the three groups*

Time	G I No ICM (n = 20)		G II Metapaste (n = 20)		G III Metapex (n = 18)		*P*-value	*Effect size (Eta squared)*
	Median	Mean (SD)	Median	Mean (SD)	Median	Mean (SD)		
Pre-operative	5 (2-10) ^{A}	5.1 (2.47)	5 (2-10) ^{A}	5.1 (2.05)	5.5 (3-10) ^{A}	5.89 (2.08)	0.306	0.028
4 hrs.	3.5 (0-10) ^{B}	4.1 (2.61)	4.5 (0-10) ^{B}	4.5 (2.74)	5 (0-10) ^{A}	5.44 (2.79)	0.357	0.042
6 hrs.	5.5 (0-10) ^{A}	4.7 (3.29)	5.5 (0-10) ^{A}	5.2 (3.11)	6 (0-10) ^{A}	5.78 (3.21)	0.616	0.019
12 hrs.	6 (0-10) ^{A}	4.6 (3.45)	6 (0-10) ^{A}	5.3 (3.11)	6 (0-10) ^{A}	5.72 (3.32)	0.628	0.02
24 hrs.	5 (0-10) ^{A}	4.3 (3.26)	3.5 (0-10) ^{C}	3.6 (3.33)	6 (0-10) ^{A}	5.94 (3.26)	0.327	0.043
48 hrs.	3 (0-10) ^{B}	3.25 (2.88)	3.5 (0-10) ^{C}	3.6 (3.33)	3.5 (0-10) ^{B}	4.06 (3.46)	0.796	0.011
72 hrs.	3 (0-10) ^{B}	2.95 (2.89)	3 (0-8) ^{C}	2.7 (2.72)	3 (0-8) ^{B}	2.5 (2.6)	0.949	0.005
1 week	3 (0-6) ^{B}	2.2 (2.14)	0 (0-10) ^{D}	2 (3.61)	0 (0-4) ^{C}	0.67 (1.33)	0.064	0.066
P-value	<0.05*		<0.05*		<0.05*			
Effect size (w)	0.281		0.455		0.627			

**: Significant at P ≤ 0.05, Different superscripts in the same column indicate statistically significant change by time*

DISCUSSION

Teeth with infected necrotic pulp harbors several bacterial species, especially strictly anaerobic bacteria, have greater incidence of flare-ups. Also, significant post-operative pain and flare-ups are predicted in symptomatic cases. Intracanal medication is used in such cases for neutralizing the bacterial endotoxins and arresting the microbial proliferation[10]. Calcium hydroxide was used in the present study as a universal intracanal medication [3]. Its premixed pastes are easy to use and commercially available.

A simple-spoken classification in terms of MVAS was used, which represents the pain visually, verbally, and numerically with high reliability and validity to the patients [11].

In this study, care was taken to rule out any aggravating factors that may interfere with the results and to minimize any inevitable cause of post-endodontic pain. In the current protocol, established root canal length was maintained 0.5 mm short of the anatomic apex as detected by electronic apex locator as well as confirmed by digital periapical radiograph. Chemomechanical preparation was performed meticulously to limit debris and irrigating solution as possible from extrusion beyond the apex [12].

A lack of significance was detected between the mean age and gender values among the groups. These results were in accordance with several studies [13,14], which claimed the absence of correlation between these variables and post-operative pain. Whereas contradictory studies showed that post-endodontic pain has positive correlation with older age groups, and female gender [1, 15]. Therefore, the impact of demographic data on post-operative endodontic pain is still controversial.

The intragroup analysis of the present results showed a significant change in pain within each group by time, which decreased to minimal levels after one week. This is consistent with ***Pak et al.*** [16] and ***Wagh et al.*** [17].

At 4 hrs post-operatively, results revealed significant decrease in post-operative pain within G II (Metapaste group) and G I (control group), followed by a rise in pain significantly at 6 hrs. post-operatively which might be resulted from the inflammatory reaction that takes some hours to reach its peak after intervention [18]. There was significant decrease from 12-24 hrs only within Metapaste group that could be attributed to the slow rate of ionic liberation of the calcium hydroxide in viscous vehicle however, it is faster than calcium hydroxide with oily vehicles as Metapex. On the other hand, G III (Metapex group) had no significant change till the first 24 hrs followed by significant decrease from 24-48 hrs. this might be referred to the combination with iodoform and silicon oil as vehicles, which delays the action of the medicament [19]. ***Omaia et al.*** [20] and ***El Abbasy et al.*** [21] support these results.

No significant change was found within the control group at 48, 72 hrs. as well as after one week, however there is significant decrease in the other two groups that could be linked to the prolonged duration of the action of calcium hydroxide in both formulations [19, 22].

The null hypothesis was ascertained in the current study since there was lack of significance in post-endodontic pain scores among all groups throughout all time intervals. The lack of significance between G II and G III revealed that the two formulations of calcium hydroxide intracanal medicament have similar effect on post-operative pain. Moreover, lack of significance between the two experimental groups as well as the control group could infer a neutral effect of calcium hydroxide on post-endodontic pain.

A further explanation for the lack of significance between groups is that shaping and obturation have greater influence on post-operative pain than intracanal medications if the medication is kept throughout the confine of the root canal system. Therefore, extrusion of endodontic materials apically and tissue injury through root canal intervention mechanically or chemically have greater effect on pain initiation or persistence. This was reflected in similar outcome between the experimental and control group, and in accordance with ***Narayanan et al.*** [23] revealing a comparable analgesic property of calcium hydroxide to the no intracanal medicament group. ***Trope*** [24] also confirmed the non-relevant antibacterial effect of the medicament to the incidence of flare-ups after chemo-mechanical preparation.

Although iodoform has antibacterial effect and it is added to calcium hydroxide as biological active component [4], it has no significant effect on post-operative pain reduction; Even it has negative impact on post-operative pain in some studies[25,26]. It could be justified by the harmful side effect of iodoform at the contact area to the apical living tissue that can cause mild inflammation or tissue edema [27] .

The results of the current study were in harmony with ***Walton et al.*** [28] who supported the weak correlation between calcium hydroxide and post-operative pain reduction. Furthermore, reporting that calcium ions have been shown to reduce pain through inhibition of nerve activity conduction together with the antimicrobial activity both failed to reveal any conspicuous clinical effect on post-operative pain reduction.

In contrast to the presented neutral effect of calcium hydroxide on post-operative pain, ***Omaia et al.*** [20] concluding a negative impact of calcium hydroxide on post-operative pain, with higher significant post-operative pain in Metapex group in comparison to the other experimental intracanal medication (TAP with diclofenac potassium) at 48 hr. They further doubted the role of calcium hydroxide in eradicating bacteria associated with apical infections because of the buffering effect of dentinal tubules' microorganisms on calcium hydroxide's high pH.

Furthermore, ***Sirry et al.*** [29] recommended propolis as a substitute intracanal medicament to Metapaste to control post-operative pain because of its higher antimicrobial activity and biocompatibility. On the other hand, the anti-bacterial efficacy of calcium hydroxide showed to be lower than other herbal intracanal medicament like garlic extract [30].

The results were also in contradiction with ***Thakur et al.*** [25] who claimed that calcium hydroxide paste group recorded the least post-operative pain at 12, 24 hrs over calcium points followed by $Ca(OH)_2$ combined with 0.2% chitosan, $Ca(OH)_2$ combined with iodoform and control group . Additionally, the highest post-operative pain was evident in the $Ca(OH)_2$ combined with iodoform (Metapex) group at 6 hrs. Moreover, ***Aggarwal et al.*** [26] revealed that the reduced post-operative discomfort at 12 hrs., 24 hrs. and 48 hrs. following the procedure was in calcium hydroxide with polyethylene glycol-based paste group with the maximum post-operative pain in the control group. The contradictory results between the current study and the previous two studies could be related to two reasons, first of which is the case selection, vital teeth, teeth with sinus tract, teeth that were diagnosed with irreversible pulpitis whether accompanied or not with apical periodontitis, teeth that had periapical bone resorption, and teeth with Grade – 1 mobility were included in both studies and at the same time they were excluded in the current study. The second reason for this contradiction is using different commercial types of calcium

hydroxide with different viscous vehicles in their composition. Each vehicle has its own criteria and could affect $Ca(OH)_2$ physically and chemically.

CONCLUSION

Based on the results of this study, it could be concluded that calcium hydroxide with or without iodoform has a neutral effect on post-endodontic pain in cases initially diagnosed with necrotic pulp and symptomatic periodontitis. Further studies based on molecular investigations such as inflammatory mediators assessment in relation to the post-operative pain after using both formulations of calcium hydroxide are recommended.

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